



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,132	10/29/2001	Donald E. Bobo JR.	CVG-5637	2468

7590

11/25/2005

Debra D. Condino
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, CA 92614

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,132

Applicant(s)

BOBO, DONALD E.

Examiner

david shay

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 6, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 14, 2002z is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2005 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “introducing the catheter through an endoluminal entry point”; “supportively engaging the medicament delivery catheter with the atrial septum at the opening and sealing the opening...and creating a channel through the surface of the heart chamber...”; and “providing a medicament delivery catheter having a first and a second balloon and a tissue engaging surface with a third balloon” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed September 2, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "supportively engaging the medicament delivery catheter with the atrial septum at the opening and sealing the opening...and creating a channel through the surface of the heart chamber..." (there is no discussion of ablating subsequent to sealing the opening in the septum) and "providing a medicament delivery catheter having a first and a second balloon and a tissue engaging surface with a third balloon".

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36-38 and 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent on

“supportively engaging the medicament delivery catheter with the atrial septum at the opening and sealing the opening...and creating a channel through the surface of the heart chamber...”
and “providing a medicament delivery catheter having a first and a second balloon and a tissue engaging surface with a third balloon”

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-38 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 36 “the right atrium” and “the chamber of the heart” both lack positive antecedent basis. In claim 45 “the circulatory system”; “the right atrium”; “the atrial septum”; “the opening”; “the chamber”; “the heart”; and “the deployable tissue stabilizer” all lack positive antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Flaherty et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3735

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al in combination with Cox et al, and Kalloo et al. Jenkins et al teach a method as claimed (column 1, line 20 to column 2, line 54). Cox et al teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a bleeding heart. Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device. It would have been obvious to the artisan of ordinary skill to, in order to wedge the probes in the method of Jenkins et al, to employ the balloons of Kalloo et al, since this would both stabilize the devices as well as seal the opening, which is desirable, since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox et al, thus producing a device and method such as claimed.

Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al in combination with Cox et al, and Kalloo et al as applied to claims 36-38 above, and further in view of Alt. Alt teaches the use of a balloon to seal tissue and prevent washout. It would have been obvious to the artisan of ordinary skill to employ a balloon against the tissue surface, since this will prevent washout, as taught by Alt, thus producing a method such as claimed.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller ('523) in combination with Jenkins et al. Mueller ('523) teach sealing to the cardiac tissue using a vacuum port before creating a channel in the tissue. Jenkins et al teach injecting drugs into channels created in the myocardium. It would have been obvious to the artisan of ordinary skill

to employ the drug injection of Jenkins et al in the method of Mueller ('523) since this is desirable to help maintain the channels, as taught by Jenkins et al, thus producing a method such as claimed.

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller ('523) in combination with Jenkins et al as applied to claims 39 and 40 above, and further in view of Jeevanandam et al. Jeevanandam et al teach the use of multiple vacuum ports to secure a channel-forming device to the cardiac wall so as to form chambers therein. It would have been obvious to the artisan of ordinary skill to provide multiple ports, as taught by Jeevanandam et al, since this provides secure fixation and to provide four ports, since the number of ports can be varied as desired, as taught by Jeevanandam et al, thus producing a method such as claimed.

Applicant argues that the combination of Jenkins et al, Ryan et al and Cox et al with or without the addition of Kalloo et al. However, applicant has merely argues the references in a piecemeal fashion, disregarding the examiner's motivations for combination and alleging in effect that since none of the references teach each and every limitation of the claims, they cannot be combined to render the invention obvious.

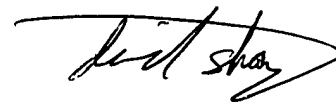
Applicant's arguments filed September 2, 2005 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 36-45 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam, can be reached on Monday, Tuesday, Wednesday, and Thursday at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330